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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,933	07/29/2003	Anandan Palani	IN01481KC	7512

24265 7590 06/17/2005

SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
2000 GALLOPING HILL ROAD  
KENILWORTH, NJ 07033-0530

EXAMINER
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CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/628,933

Applicant(s)

PALANI ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 29 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 21-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 21-40 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. This application is a divisional of SN 10/229,466. Claims 1-20 have been canceled. Claims 22-40 are pending.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 24, drawn to compounds of formula (I) wherein both R1 and R2 are nonheterocyclic, R3 is substituted or unsubstituted pyrimidine, classified in class 544, and subclass 360 depending on species election. If this group is elected a further election of a single disclosed species is also required. Claims 21-23, 25-30 pharmaceutical composition can be prosecuted with the elected compounds to the extend that both R1 and R2 are nonheterocyclic.
- II. Claim 23 wherein R1 is piperidine, R3 is substituted or unsubstituted pyrimidine drawn to compounds classified in class 544 and subclass 364, depending on species election. If this group is elected a further election of a single disclosed species is also required. If this group is elected a further election of a single disclosed species is also required. Claims 21-22, 25-30 pharmaceutical composition can be prosecuted with the elected compounds to the extend that R1 is piperidine.
- III. Claims 21, 25-30 drawn to compounds of formula (I), pharmaceutical composition wherein R3 is substituted or unsubstituted heteroaryl not encompassed by groups I or II, classified in class various and numerous subclass depending species election. If this group is elected a further election of a single disclosed species is also required. Further restriction based on the elected species may be required.
- IV. Claims 31-33 drawn to methods of treating human immunodeficiency virus, classified in class 514, subclass various depending on species election. If this group is elected a further election of a single disclosed active compound for the method is also required.
- V. Claims 34-36, drawn to methods of treating human immunodeficiency virus employing compounds of claims 1 or 4 and additional one or more antiviral or

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other agents, classified in class 514, subclass various depending on species election. If this group is elected a further election of a single disclosed "combination" of one active compound with every active ingredient in the combination named, for the method is also required.

- VI. Claims 38-39, drawn to method of treating solid organ transplant rejection, graft v. host disease, arthritis.....etc., using single or multiple active ingredients classified in class 514, subclass various depending on species election. If this group is elected, a further election of a *single disclosed disorder* together with a single active ingredient alone or a single disclosed "combination" of one active compound with every active ingredient in the combination named, for the method is also required.
- VII. Claim 40, drawn to pharmaceutical "kit" i.e. medicinal packaging, classified in class 206, subclass 828.

Inventions I-III compounds differ in chemical structure and properties to such an extend that a compound anticipating any of the groups I-III does not render another group obvious. The classification and search of each group is not coextensive with each other and the enormous class and subclasses required to be search for each group can not be ascertained until a species election can be made. The search and examination of the prior art is extremely burdensome were restriction not made. Upon election of a single disclosed species reading on the group, a determination will be made on the generic concept of common "class" based on art recognized common core. A clear statement of scope for examination will be set forth in the first action on the merits.

Should applicant traverse on the ground that the groups/species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the groups/species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Groups I-III compounds per se and groups IV-VII are independent and distinct because the method of treating HIV, other disorder i.e. organ transplant rejection etc. or medicinal kit are not the same categories of invention. The use of single or multiple active ingredients in treating

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diseases are also patentably distinct and separate searches must be conducted. The enormous burden of searching extremely diverse classes and subclasses without restriction has been delineated supra since various classes and subclasses must be searched independently together with electronic or nonelectronic searches of literature with each and every ingredient as it relate to the disorder.

The compounds of group I have been elected prosecuted in the parent application. Applicant is advised *that the reply to this requirement to be complete must include an election of the remaining invention to be examined* even though the requirement be traversed (37 CFR 1.143).

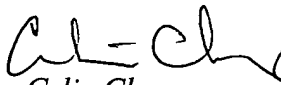
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

2. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Jun. 14, 2005

  
Celia Chang  
Primary Examiner  
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